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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,215	02/19/2004	James A. McClain	030900	5338

41835 7590 11/01/2007  
KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP  
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PITTSBURGH, PA 15222

EXAMINER
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KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/782,215

**Applicant(s)**

MCCLAIN, JAMES A.

**Examiner**

Ganapathy Krishnan

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7,9,10,12-16,18-24,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Amendment after Final filed 03/05/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2, 5, 8, 11, 17 and 25 have been canceled.
2. Claims 1, 15-16, 24 and 26-27 have been amended.
3. Remarks drawn to claim objections and rejections under 35 USC 112, first paragraph, 102 and 103.

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 are pending in the case.

The finality of the Office Action mailed 05/31/2007 has been withdrawn and the following rejection is made of record.

#### ***Claim Objections***

The objection to claim 27 has been withdrawn in view of applicants' arguments.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making resistant starch with a whiteness level of 65, does not reasonably provide enablement for making resistant starch having

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a whiteness level above 65 using the conditions as instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The level of one of ordinary skill
- (C) The amount of direction provided by the inventor
- (D) The existence of working examples
- (E) The level of predictability in the art
- (F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

The recitation in the instant claims namely, a whiteness level of at least 65, which means that the whiteness level can be above 65.

**The level of one of ordinary skill in the art**

The level of skill of those in this art is that of one having experience in organic synthesis.

**The amount of direction provided by the inventor**

The specification (page 8) recites that the heating is done at temperatures between 140 and 180°C. This means that any temperature in the said range can be used to produce the starch with the whiteness level in the range 60-100.

**The existence of working examples**

The working examples set forth in the instant specification are drawn to heating of acidified corn starch to 140, 150 and 170°C until a whiteness level of 65 is reached. Even though the examples are not limited to the target whiteness level of 65, applicants' examples do not show that a whiteness level of greater than 65 can be achieved especially based on the disclosure of Ohkuma.

**The level of Predictability in the Art**

Ohkuma et al (US 5,358,729; used in the rejection below) teaches that there is an inverse relationship between whiteness and temperature (col. 23, Table 13). The process of Ohkuma is same as used instantly with the pH seen to be very close to the range as claimed in the instant process. In the example of Ohkuma heating at 170°C produces starch with a whiteness level of 21.2. It is uncertain from this disclosure if a whiteness level of greater than 65 could be attained if the heating is prolonged at these temperatures. It is not predictable that if a higher level of whiteness can be attained if temperatures above 170°C are used since temperature that high can cause degradation and caramelization, which can produce coloring (Ohkuma, col. 6, lines 62-68). Because of this uncertainty undue experimentation is necessary.

**The quantity of experimentation needed to make or use the invention based on the content of the disclosure**

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to represent the process as instantly claimed for making resistant starch with the level of whiteness greater than 65 at temperatures as instantly claimed. One of ordinary skill in the art would have to carry out undue experimentation to practice the instant invention.

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***Claim Rejections - 35 USC § 102***

The rejection of Claims 1, 3, 6-7, 13-16, 21, 23-24 and 27 under 35 U.S.C. 102(b) as being anticipated by Ohkuma et al (US 5,358,729) of record has been overcome in view of applicants' amendments and arguments.

***Claim Rejections - 35 USC § 103***

Claims 4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohkuma et al (US 5,358,729) of record has been overcome in view of applicants' amendments and arguments.

***Conclusion***

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24 and 26-27 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

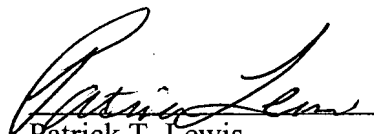
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



Patrick T. Lewis  
Primary Patent Examiner  
Art Unit 1623